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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,748	02/22/2002	Joshua A. Bischoff	BHF-101-A	9975

7590 07/25/2003  
YOUNG & BASILE, P.C.  
Suite 624  
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Troy, MI 48084

EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/25/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/080,748

Applicant(s)  
Bischoff

Examiner  
Joseph Weiss

Art Unit  
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 22, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) \_\_\_\_\_
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152) \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 & 9, line 1, what is "its"?

In claim 1, line 2 the phrase "in combination" renders the claim indefinite, is applicant claiming the combination of the device and a tube or just the device alone. The pre-amble starts by solely claiming the device, re-enforces this with "adapted to language" but then uses the "in combination" phrase in an awkward manner that renders the status of the claim being drawn solely to the subcombination in doubt.

Use of the relative term "outer" to describe the tube end renders the claim indefinite. Standard in the art is to use patient end/machine end or distal end/proximal end, the latter in each set corresponding to what applicant appears to be referring to as the "outer end"

3. Claims 1 & 9 recites the limitation "the appearance" in the last line. There is insufficient antecedent basis for this limitation in the claim.

In regards to the end of claim 6, in regards to "thereto" what is "thereto referring to?"

In regards to claim 7, lines 1-2 the phrase "to the pipe outer" [end]??

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4. Claim 7 recites the limitation "the wearer's neck" in line 2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 13 recites the limitation "said base" in line 1. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 14 recites the limitation "the visible dimension" in line 1. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 14 recites the limitation "the same" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 14 recites the limitation "the diameter" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2, 4-11 & 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rangoni et al (US 4809693).

In regards to claim 1, Rangoni discloses an aesthetically pleasing low profile tracheostomy device (See any fig) adapted to be mounted on a tracheostomy pipe outer end (See

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any fig note interface between structure 3 and tube 1) having a low profile housing (10) mounted upon the pipe outer end having an inlet port (defined by end of housing 10 w/ flange/projection 11) in communication with a check valve (6/9), a check valve (6/9), and an outlet port (defined end of housing 10 opposite end with flange/projection 11) in communication with the pipe outer end and a decorative cover mounted on the housing (12) enclosing said housing and giving it the appearance of neck jewelry.

In regards to claim 2, Rangoni discloses the housing being removably attached to the outer end of the pipe (note friction fit interface between 25 & 10).

In regards to claim 4, Rangoni discloses the check valve comprising a substantially flat flexible element (6).

In regards to claim 5, Rangoni discloses the check valve as comprising a substantially flat flexible element hinged to said housing (See sub-element 7 of 6).

In regards to claim 6, Rangoni discloses said housing having a central axis (note unlabeled central bisecting line through all components of the housing) said flat flexible check valve element having an axis parallel to said housing central axis and offset with respect thereto.

In regards to claim 7, Rangoni discloses a decorative flexible necklace attached to the pipe outer end and adapted to encircle the wearer's neck. (5, see fig 2 )

In regards to claim 8, Rangoni discloses said necklace having ends and a supported mounted upon the pipe outer end (3), the support having ends (4) and a necklace end being affixed to a support end.(col. 2 line 17)

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In regards to claim 9, is rejected IAW (in accordance with) the rejection to claims 1-2, 4-8 which is herein incorporated by reference.

In regards to claim 10, the necklace ends of Rangoni chain 5 are fully capable of being deattached from the support ends (4).

In regards to claim 11, the check valve comprises a seat (9) and a substantially flat valve element (6) cooperative with said seat to close the check valve.

In regards to claim 13, Rangoni discloses decorations (13) on said base surface.

In regards to claim 14, Rangoni discloses the dimensions of the valve housing being approximately the same as the pipe opening's diameter.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rangoni.

In regards to claims 3, Rangoni discloses a spring clip & slot fitting arranged on the outer periphery of the housing as the unifying & securing means of the device, the reference noted above substantially disclose the claimed invention except for the use of threads on the outer periphery of the housing for the same purpose as the prior art's spring clip/slot fitting and which

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are interchangeable mechanically equivalents. It is noted that applicant's specification does not set forth this mechanically equivalent interface structure as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rangoni as applied to claim 8 above, and further in view of Smith (US 5606966).

In regards to claim 12, Rangoni substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of circular threads on the periphery of the housing and a decorative cover having an internal threaded lip cooperating with said housing periphery threads and a base extending between said lip. However, Smith disclose such (cover 12, with lip and internal threads and valve housing 4 having periphery threads). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Smith and used them with the device of Rangoni. The suggestion/motivation for doing so would have been to because threading and spring clipping are



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known interchangeable mechanical equivalents. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

### *Conclusion*

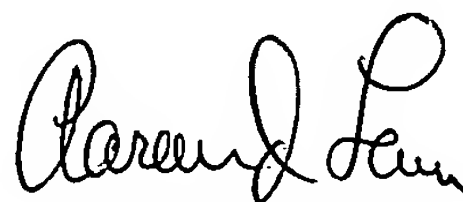
14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5738095, 566950, 5060645, 5059208, 4759356, 4582058, 4538607, 4325366, 4040428, 3844290, 2786469

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun LO, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. F. Weiss

July 18, 2003



Aaron J. Lewis  
Primary Examiner